

RANDOMISED CONTROLLED CLINICAL TRIAL OF DARVI TAILA IN DUSHTA VRANA W.S.R. TO INFECTED WOUND

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ABSTRACT :

Today's world which is full of hustles, accidental / traumatic wounds have become very common. The modern surgical science is also well developed and hence number of surgeries being performed have grown in exponential manner. Thus care of *Vrana* (wound) has become more important than ever. Many formulations available as per modern point of view like betadiene, hydrogen peroxide, Eusol etc but these formulations causes harm to normal tissues..*Aacharya Sushruta* mentioned the management of wound in *Shashti Upkrama*. *Darvi taila* is one of the drug given by *Aacharya Charak* in *Dushta Vrana* for local application. Its efficacy is not yet evaluated in *Dushta Vrana*. *Darvi* having *Tikta, Katu rasa ,Ushna Veerya* and *Katu Vipaka* with *Laghu* and *Ruksha guna* helps in *lekhan* of wound thereby reduces discharge from wound. *Darvi* has *Tikta Katu Rasa* so these rasa acts as a *Shodhan* of Infected wound .*Taila* used is in *vyadhipratyanik* for vitiated *dosha*, alleviated *vata* is reduced from wound. *Taila* have *Madhura rasa* promotes strength and lustre alleviates *pitta* and *vayu* and pacifies heat ultimately promotes healing process. So in present clinical study evaluation of *Darvi Taila* in *Dushta Vrana* with special reference to Infected Wound is evaluated. At the end of study, it is found that local use of *Darvi Taila* in *Dushta Vrana* is effective than Betadiene with respect to *Vedana, Daha, Shotha, Gandha, Srava, Granulation*. Thus at the end of study it implies that use of this drug minimise the wound infection.

Key words: *Dushta Vrana. Darvi Taila vyadhipratyanik*

INTRODUCTION : *Vrana* (wound) management is the backbone of *Shalyatantra* i.e. Surgery. A surgeon must be an expert in comprehensive care of *Vrana* management. *Sushruta*, on of the most ancient surgeon has dedicated a large part of *Sushrut-Samhita* narrating various aspects of *Vrana* management. *Aacharya Sushruta* also described many surgical practices like *Ksharakarma, Agnikarma* and *Raktamokshana*. But he described *Shasti Upakrama* in detail and in a very scientific manner. There are several basic principles of *Aacharya Sushruta* which are the roots of today's surgery and provides guidelines to modern surgery.

The principles mentioned in *Shasti Upkrama* for the management of wounds to modern surgery and reduces its complications. *Aacharya Sushruta* mentioned *Shasti Upakrama* in *Chikitsa Sthana* giving its prime importance. considering all these we can say that *Vrana* and its management are the central focus in *Shalyatantra*.

This wound management aims at first to transform an infected wound into clean wound. Various techniques and medications are used for this. As per modern treatment, main aim to reduce the infection in wounds also management of chronic wounds, non-healing ulcers, venous ulcers is big task because removal

of micro-organisms and dead tissue is essential in chronic wounds. Enhancement of healthy normal tissue for proliferation and care of delicate structures like granulation tissue, fibroblasts, collagen, epithelium are important. Wound care from modern medicines with hydrogen peroxide, iodophores not only destroys micro-organism but also provides harm to delicate structures in wounds. In such cases local application of Ayurvedic preparations can prove their efficacy in the management of chronic and infected wound. Ayurveda has an advantage in this area. *Shodhana* i.e. transformation of infected wound / ulcers into clean healing wound. Lots of formulations regarding *Vranashodhana* are scattered in all ancient. In *Charak samhita* the *Darvi taila* is used in the treatment of *Dushta Vrana* as a local use. *Taila Kalpana* has been described by *Acharya Sushruta* as one of the *Shasti Upakramas* which can be used for *Shodhana and Ropana karma* of *Dushta Vrana*. So in this clinical study, we have decided to evaluate clinical efficacy of *Darvi Taila* in *dushta Vrana* with special reference to infected wound.

2. AIMS AND OBJECTIVES

1. To achieve transformation of *Dushta Vrana* into *Shuddha Vrana* to achieve rapid wound healing.
2. To study concept of *Dushta Vrana* in Ayurvedic as well as modern point of view.
3. To find a better alternative medication for *Vranashodhana*.
To avoid complication of *Dushta Vrana* by converting it into *Shuddha Vrana*.
4. The aim proposed clinical studies to correlate the management of *Dushta Vrana* based on principles in Ayurveda and practices mentioned in modern sciences.

3. MATERIALS AND METHODS :

MATERIALS :

1. SELECTION CRITERIA OF PATIENT:

A) INCLUSION CRITERIA:

- 1) All Patients irrespective of sex presenting with features of *Dushta Vrana* like *Prabhutavedana, Atisrava, Durgandha, Shotha*, etc.
- 2) Age group:- 20-60 years
- 3) Patients with wound area less than 20 sq.cm. and *twak and mansa* as *Vravavastu*.

B) EXCLUSION CRITERIA:

- 1) *Shuddha Vrana*.
Known case of following diseases-
- 2) Bone deep ulcers.
- 3) Compound fracture
- 4) Ulcers with osteomyelitis
- 5) Leprotic ulcers
- 6) Ischaemic ulcers
- 7) Severe anaemia
- 8) Renal failure
- 9) Hepatic failure
- 10) Steroid dependent patient

Darvi Taila : *Darvi Taila* is prepared at *Rasashatra and Bhaishjya kalpana* department of *Arogyashala Hospital, A.S.S Ayurved Mahavidyalaya, Nasik* by *Tailpak Vidhi* mentioned in *Sharangdhar samhita*.

Clinical Methods : The study was conducted in O.P.D. and I.P.D. of *Shalyatantra* department in *Arogyashala Hospital, A.S.S Ayurved Mahavidyalaya, Nasik*. Total 60 patients selected randomly as per the following criteria into two groups namely Group A (Experimental Group) and Group B (Control Group). 30 patients were treated with each groups.

1. Group A (Experimental Group-Darvi Taila) :-

Application :

Dose : According to wound size..

Route of administration: Local application..

Follow Up: On 0,5,10,15 day.

Time of dressing: Daily.

Duration: 15 Days or which is earlier.

2. Group B (Control Group-Povidone iodine) :

Application :

Dose : According to wound size..

Route of administration: Local application..

Follow Up: On 0,5,10,15 day.

Time of dressing: Daily.

Duration: 15 Days or which is earlier.

SYMPTOMATIC CLINICAL ASSESSMENT:

No.	Criteria	Gradation	Score
1	VEDANA	Absent	0
		Mild pain (does not require analgesics)	1
		Moderate pain (require oral analgesic)	2
		Severe pain (require parenteral analgesic)	3
2	DAHA	Absent	0
		Mild (only during dressing)	1
		Moderate(daha but do not disturb daily activities)	2
		Severe (Disturb daily activities)	3
3	SHOTH	Absent	0
		Mild (Limited to margin of wound)	1
		Moderate (0-3cm surrounds from wound margin)	2
		Severe (>3cm surrounds from wound margin)	3
4	Charmcheli formation	Healthy granulation all over wound (>75%)	0
		Healthy granulation over most of area of the wound (51-75%)	1
		Partial granulation (0-50%)	2
		No granulation tissue at all	3
5	SRAVA	Absent	0
		Serous	1
		Seropurulent (Shwet)	2
		Purulent (Yellow)	3
6	GANDHA	Nirgandha	0
		Durgandha	1

INVESTIGATIONS:Following investigations will be carried out for each patients treated in the proposed study.

1)CBC, 2)BSL (Random) as & when required

OBSERVATIONS AND RESULTS

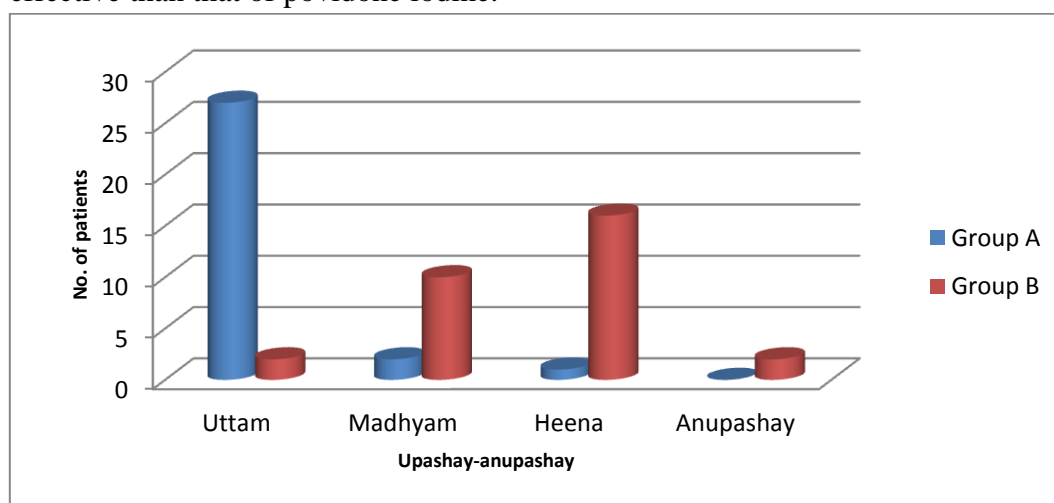
No.	Symptom	χ^2	df	Table value	χ^2	Probability	Result
1	VEDANA	6.9	2	5.99		>0.05	Significant
2	DAHA	7.52	2	5.99		>0.05	Significant
3	SHOTH	7.52	2	5.99		>0.05	Significant
4	Charmcheli	6.9	2	5.99		>0.05	Significant
5	SRAVA	7.96	2	5.99		>0.05	Significant

6.Gandha :-For this criteria non-parametric Run test is applied.

Sr.No.		Experimental Group	Control Group
1.	Run Value	10	11
2.	Positive Value(n1)	22	24
3.	Negative Value(n2)	8	6
4.	Lower Critical Value	7	6
5.	Upper Critical Value	17	13
6.	Result	$A < r < B$	$A < r < B$
		Significant	Significant

Distribution of patients according to total effect of therapy

From the above graphical representation, we can see the Gr. A i.e. *Darvi Taila* application is more effective than that of povidone iodine.



DISCUSSION: Complete assessment of all patients is done by using various standard statistical methodology with each and every follow up. Following discussion is made after complete assessment

1.Vedana : There was no significant difference found in control and experimental group on day 5 and day 10 . Significant difference was observed in experimental group and control group on Day 15 .At the end of study, from Gr. A 23 patients shows Uttam upashaya, 6 shows Madhyam and 1 shows Heena upshaya.

2.Daha:There was significant difference in shotha of wound in control and experimental group on Day 5, Day 10 and Day 15. At the end of study, from Gr. A 20 patients shows Uttam upashaya,6

shows Madhyam and 4 shows Heena upshaya
3) Shotha :There was significant difference in shotha of wound in control and experimental group on Day 5, Day 10 and Day 15. At the end of study, from Gr. A 20 patients shows Uttam upashaya,6 shows Madhyam and 4 shows Heena upshaya

4) Srava:Significant difference was observed in experimental group and control group on Day 10 and Day 15. There was no significant difference in Srava of wound Day 5. Control experimental group is more effective on Day 10 and day 15. At the end of study, from Gr. A 20 patients shows Uttam upashaya, 6 shows Madhyam and 4 shows Heena upshaya..

5) Charmcheli Formation (Granulation tissue formation):

There was no significant difference found in control and experimental group on day 5 and day 10 . Significant difference was observed in experimental group and control group on Day 15 .At the end of study, from Gr. A 23 patients shows Uttam upashaya, 6 shows Madhyam and 1 shows Heena upshaya.

6) **Gandha** Study shows significant result from D5 and it is more significant at the end of D15.*Darvi Taila* is *Ushna Veerya* and *Katu Rasatmaka* causes *lekhan karma* of wound there by causes wound contraction results in decrease in *gandha* of *Dushta Vrana*.

Probable mode of action of Darvi Taila (Ayurvedic View)

1.*Darvi* having *Tikta, Katu rasa, Ushna Veerya* and *Katu Vipaka* with *Laghu* and *Ruksha guna*. The *Laghu, Ruksha guna* helps in *lekhan* of wound thereby reduces discharge from wound. Means these *gunas* makes wound dry so enhance wound healing.

2.It can be stated that the content of *Darvi Taila* causes chemical debridement in the form of decreasing necrotic tissue .In turns it reduces the *srava* as well as foul smell and helps to make the wound healthy granulated.

3.*Darvi* has *Tikta Katu Rasa* so these *rasa* acts as a *Shodhan* of Infected wound .

4.*Taila* used is an *vyadhipratyanik* for vitiated *dosha*, alleviated *vata* is reduced from wound. *Taila* have *Madhura rasa* promotes strength and luster alleviates *pitta* and *vayu* and pacifies heat ultimately promotes healing process.

Probable mode of action of Darvi Taila (Modern View)

1.Proper healing of wound is essential for restoration of anatomical continuity and disturbed functional status of the skin. A

drug used in management of *Dushta Vrana* causes wound contraction and complete epithelization of wound.

2.Active principle present in *Darvi* is Berberine.It improves the appearance of non-healing ulcers and promotes cicatrization. It is active against variety of micro-organisms having antimicrobial property.

3.Berberine acts by blocking early release mediators ie prostaglandins as well as blocking the late mediators ie bradykinin, histamine etc ultimately reduces inflammation causes contraction of wound and forms epithelization leads to healing of wound.

CONCLUSION:

Conclusion from entire research study has been discussed as follows :-

1. As per clinical observation during study *Darvi Taila* was effective than povidone iodine for the management of *Dushta Vrana*.

2. In clinical study there was reduction in discharge due to *katu rasa* of *Daruharidra* and cause early *shodhana* and *Ropana karma*.There was reduction of *vedana* due to *ushna veerya* of *Darvi*.

3. Clinical observation of *Darvi taila* promotes granulation tissue formation, wound contraction and improves microcirculation.

5. *Darvi taila*, a ayurvedic preparation which is oil based are not adherent to wound tissue and provides good adhesiveness to tissue which may helps for better cross linking of collagen fibres for collagen formation. it provides moist environment may help for early epithelialization and granulation tissue formation.

7. Berberine possesses a antimicrobial activity against following species of an

organism Eg. E.coli, S.typhimurium, S.dysenteriae, V.cholerae

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Declared

